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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,295	03/22/2004	Paulo LaColla	06171.105033 (IDX 1008 DI	1837

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EXAMINER
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ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,295	LACOLLA ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,12,13 and 19-64* is/are pending in the application.

4a) Of the above claim(s) *8,9,12,13,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24 and 27-64* is/are rejected.

7)☒ Claim(s) *47,48 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/01/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Election and the Amendment filed August 15, 2005. Claims 30-64 have been added. Claims 8-9, 12-13 and 19-64 are pending. Claims 8, 9, 12, 13, 25 and 26 are withdrawn from consideration. Claims 19-24 and 27-64 are examined herein.

Election/Restrictions

Applicant's election without traverse of Group III, drawn to a method of treatment or prophylaxis of HIV infection, in the reply filed on August 15, 2005 is acknowledged. Claims 8, 9, 12, 13, 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The species requirement set forth in the restriction requirement dated July 12, 2005 is hereby withdrawn.

Claim Objections

Applicant is advised that should claim 45 be found allowable, claims 47, 48 and 56 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24 and 27-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of HIV infection, does not reasonably provide enablement for the prophylaxis of HIV infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) ***The Nature of the Invention***:

The invention is drawn to a composition for the prophylaxis or treatment of HIV. It is noted that the Webster's New Riverside University Dictionary (1984) defines prophylaxis as "Protective treatment for or prevention of disease." Accordingly, prophylactic treatment encompasses preventative treatment.

(2) ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claimed invention includes the prevention of HIV. Accordingly, the term "prevention" indicates a claim whereby those normally not at risk for developing an HIV infection from ever developing an HIV infection with any of the numerous compounds claimed.

(3) ***Guidance of the Specification***:

The guidance of the specification as to "prevention" of an HIV infection is completely lacking. In Table 2 of the specification, the Applicant describes the amount of a few compounds necessary to achieve 50% protection and the amount required to reduce the amount of p24 by 90% in virus infected cells. There is no indication, however, that complete prevention is attainable.

(4) ***Working Examples***:

As discussed in the Guidance of the Specification section, Applicant has only shown the treatment of HIV claimed to be preventable by the instant invention.

(5) ***State of the Art***:

The state of the art regarding the treatment of HIV is developed. The state of the art regarding the *prevention* of HIV is underdeveloped.

Finally, reasonable guidance with respect to *preventing* HIV infection relies on quantitative analysis from defined populations which have been successfully pre-screened and are predisposed to HIV. This type of data might be derived from high risk activities, etc. It is noted, however, that a significant portion of the population is at some risk for developing HIV. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of infection with HIV and *link* those results with subsequent histological confirmation of the presence or absence of injury. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the disease.

(6) ***Predictability of the Art***:

The invention is directed to a composition capable of *prevention* or treatment of HIV in *general* with a compound of the claimed invention. It is well established that "the scope of enablement various inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970).

Also note that one of ordinary skill in the art would recognize that it is highly unpredictable in regard to what population will become infected with HIV, as discussed in (5) above. In order to administer the agent to population at large, one would need to consider the therapeutic effects, side effects and especially serious toxicity that may be generated by drug-drug interactions when and/or after administration to a living organism (e.g., a human) the divergent compounds found in the instant claims.

(7) ***The Quantity of Experimentation Necessary***:

In order to practice the disclosed invention, one would need to undergo undue experimentation to test the various of the instant specification to determine whether or not any of them are actually capable of completely preventing an HIV infection, as the instant specification does not show the complete prevention thereof.

As discussed above, the specification fails to provide sufficient support for determining all patients susceptible to HIV infection in order to allow one of ordinary skill in the art to be capable of administering to a population the claimed compounds of the instant invention for the *prevention* of an HIV infection. As a result, one of skill in the art would be forced to perform an exhaustive search for the population that will become infected with HIV and, thereby, use the instant invention.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and '[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

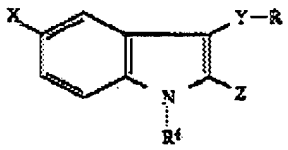
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-24, 27-32, 45, 47-51 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (USPN 5527819).

Williams et al. teaches inhibitors of HIV reverse transcriptase for the treatment of HIV infection with the formula:



R is taught to be an aryl with the same substituents as claimed. Y is taught to be $S(O)_n$ or O, as claimed. Z is selected from various amides, imines, etc., as claimed. R6 is taught to be selected from, e.g., hydrogen, as claimed. X is taught to be selected from H, Cl, F, BR, etc., as claimed. Treatment of HIV in combination with other anti-HIV agents is also taught. See Abstract; col. 1, line 14-col. 15, line 23. Williams et al. does not teach at least one of $R^{4'}$, $R^{6'}$ or $R^{7'}$ as a non-hydrogen atom.

It would have been obvious to one of ordinary skill in the art to utilize a compound, as claimed wherein $R^{4'}$, $R^{6'}$ or $R^{7'}$ is a non-hydrogen because absent

unexpected properties, adjacent homologs are generally considered to be obvious. *In re Hass*, 141 F.2d 127, 60 USPQ 548 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950). In the instant case Applicant has claimed adjacent homologs to those taught in Williams et al. because Applicant's claimed invention encompasses a treatment wherein any one of $R^{4'}$, $R^{6'}$ or $R^{7'}$ is a methyl group. With the teaching of Williams et al., one of ordinary skill in the art would expect to achieve at least similar results in the treatment of an HIV infection with the compounds of the invention disclosed therein when one of hydrogen atoms at the 4, 6 or 7 positions of the indole group are substituted with a methyl group. Furthermore, it is noted that since Williams et al. teaches the treatment of HIV in general, it would have been obvious to one of ordinary skill in the art to treat specific instances of HIV, including those as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER